UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Sesen Bio, Inc. Securities Litigation	Case No. 1:21-cv-07025-AKH
	AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS
	JURY TRIAL DEMANDED

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GLOSSARY OF DEFINED TERMS

Abbreviation	Term
AE	Adverse event
BCG	Bacillus Calmette-Guérin
BLA	Biologics License Application
CIS	Carcinoma in situ
CMC	Chemistry, Manufacturing and Controls
CRL	Complete Response Letter
CRO	Contract research organization
CSO	Contract sales organization
DILI	drug-induced liver injury
DLRC	DLRC Pharma Services
E.U.	European Union
EMA	European Medicines Agency
FDA	U.S. Food and Drug Administration
GCP	Good Clinical Practices
IRB	Institutional Review Board
MAA	Marketing authorization application
MO	Major objection
NMIBC	Non-muscle invasive bladder cancer
PDUFA	Prescription Drug User Fee Act
SEC	U.S. Securities and Exchange Commission
SmPC	Summary of Product Characteristics
SOX	Sarbanes-Oxley Act of 2002
TFP	Targeted fusion protein

Lead Plaintiffs Ryan Bibb, Rodney Samaan, Lionel Dreshaj, and Benjamin Dreshaj ("Lead Plaintiffs"), individually and on behalf of all others similarly situated, by and through their attorneys, allege the following upon information and belief, except as to those allegations concerning Lead Plaintiffs, which are alleged upon personal knowledge. Lead Plaintiffs' information and belief is based upon, among other things, their counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Sesen Bio, Inc. ("Sesen Bio" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Sesen Bio; and (c) review of other publicly available information concerning Sesen Bio.

I. NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Sesen Bio securities between December 21, 2020 and August 17, 2021, inclusive (the "Class Period"). Lead Plaintiffs pursue claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Sesen Bio is a late-stage clinical company that purports to advance targeted fusion protein ("TFP") therapeutics for cancer treatments. Its lead product candidate is Vicineum, a locally administered TFP developed as a treatment for non-muscle invasive bladder cancer ("NMIBC") that is unresponsive to treatment with bacillus Calmette-Guérin ("BCG") vaccine.

3. Vicineum is administered directly into the bladder via catheter. Vicineum contains highly toxic material that kills cells interacting with the Vicineum. According to Sesen Bio, Vicineum is supposed to only interact with cancer cells and remain exclusively in the

bladder, with the Vicineum leaving the body by urination within two hours after it enters the bladder.

4. On December 21, 2020, the Company announced that it had submitted its Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market Vicineum for the treatment of BCG-unresponsive NMIBC. Beginning on December 21, 2020 and during the following eight months Defendants made numerous materially misleading statements regarding Vicineum's purported safety, trial results, and prospects for rapid approval by the FDA and other regulators worldwide.

5. Defendants' misleading statements led to a dramatic increase in the price of Sesen Bio's publicly traded stock. Defendants took advantage of this artificial stock price increase in order to raise over $175 million of capital from investors by selling Sesen Bio stock through an "at the market" offering.

6. During the Class Period, Defendants materially misled the public by failing to disclose material risks to Vicineum's approval. Specifically, Defendants failed to disclose to investors: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; and (5) that the European Medicines Agency ("EMA") had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio.

7. On August 13, 2021, Sesen Bio announced that the FDA declined to approve its BLA for Vicineum in its current form. According to Sesen Bio, the FDA provided certain "recommendations specific to additional clinical/statistical data and analyses in addition to Chemistry, Manufacturing and Controls (CMC) issues pertaining to a recent pre-approval inspection and product quality."

8. On this news, the Company's share price fell $2.80, or 57%, to close at $2.11 per share on August 13, 2021, on unusually heavy trading volume.

9. Then, on August 16, 2021, Sesen Bio revealed additional facts regarding the extent of the FDA's concerns, including that "it appears that [the Company] will need to do a clinical trial to provide the additional efficacy and safety data necessary for the FDA to assess the benefit-risk profile, which is the basis for approval." As a result, the Company expected that it could not resubmit its BLA until 2023.

10. On this news, the Company's share price fell $0.89, or 42%, to close at $1.22 per share on August 16, 2021, on unusually heavy trading volume.

11. Then, on August 18, 2021 the health and medicine news site *STAT* published an article entitled "Sesen Bio trial of cancer drug marked by misconduct and worrisome side effects, documents show." *See* Exhibit 1. Citing "hundreds of pages of internal documents" and "three people familiar with the matter," the article detailed that the clinical trial for Vicineum was "marked by thousands of violations of study rules, damning investigator conduct, and worrying signs of toxicity the company did not publicly disclose."

12. On this news, the Company's share price fell $0.20, or 13%, to close at $1.31 per share on August 18, 2021, on unusually heavy trading volume.

13. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Lead Plaintiffs and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

14. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

16. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District.

17. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

18. Lead Plaintiff Ryan Bibb, as set forth in his previously filed certification (Dkt.. No. 38-2), incorporated by reference herein, purchased Sesen Bio securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

19. Lead Plaintiff Rodney Samaan, as set forth in his previously filed certification (Dkt.. No. 38-2), incorporated by reference herein, purchased Sesen Bio securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

20. Lead Plaintiff Lionel Dreshaj, as set forth in his previously filed certification (Dkt.. No. 38-2), incorporated by reference herein, purchased Sesen Bio securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

21. Lead Plaintiff Benjamin Dreshaj, as set forth in his previously filed certification (Dkt.. No. 38-2), incorporated by reference herein, purchased Sesen Bio securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

22. Defendant Sesen Bio is incorporated under the laws of Delaware, and claims to have its principal executive offices located in Cambridge, Massachusetts. Sesen Bio's common stock trades on the NASDAQ under the symbol "SESN."

23. Defendant Thomas R. Cannell ("Cannell") was the Chief Executive Officer ("CEO") of Sesen Bio at all relevant times.

24. Defendant Monica Forbes ("Forbes") was the Chief Financial Officer ("CFO") of Sesen Bio at all relevant times.

25. Defendants Cannell and Forbes (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The

Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

IV. BACKGROUND REGARDING SESEN BIO

26. Sesen Bio is a late-stage clinical company that purports to advance TFP therapeutics for cancer treatments. Its lead product candidate is Vicineum (also known as Vysyneum, VB4-845, or Oportuzumab monatox), a locally administered TFP developed as a treatment of BCG-unresponsive NMIBC.

A. Sesen Bio Was A Small Startup With No Sales And Limited Cash, And As A Result Its Ability To Survive As A Going Concern Was In Substantial Doubt

27. During the Class Period Sesen Bio was a cash strapped startup that sold no products and required continuous infusions of fresh investor funds in order to survive.

28. Sesen Bio was organized as a Delaware corporation in 2008. Sesen Bio conducted its initial public offering of stock in 2014 (then under the name Eleven Biotherapeutics), and it began filing periodic reports with the SEC in 2014. As of December 31, 2020 Sesen Bio had only 27 full-time employees.

29. During the Class Period none of Sesen Bio's planned products had achieved regulatory approval (*e.g.*, from the FDA in the United States, or from the European Medicines Agency in Europe). Sesen Bio was not permitted to sell its products without such approvals. As

such, as of December 31, 2020, Sesen Bio had never received any revenues from product sales. Sesen Bio had received only minimal revenues from licensing and partnership agreements.

30. Sesen Bio had a history of substantial operating losses. Sesen Bio reported net losses of $22.4 million, $107.5 million, and $33.7 million for its 2020, 2019, and 2018 years, respectively. Sesen Bio financed its operations almost exclusively through obtaining funds from investors. As of December 31, 2020 Sesen Bio had only $52.4 million of cash on hand.

31. The notes to Sesen Bio's 2020 financial statements included a "going concern" warning, stating that:

> The Company's management does not believe that its cash and cash equivalents of $52.4 million as of December 31, 2020 is sufficient to fund the Company's current operating plan for at least twelve months after the issuance of these consolidated financial statements. Given the history of significant losses, negative cash flows from operations, limited cash resources currently on hand and dependence by the Company on its ability - about which there can be no certainty - to obtain additional financing to fund its operations after the current cash resources are exhausted, substantial doubt exists about the Company's ability to continue as a going concern.

B. Sesen Bio's Prospects Depended Entirely On Near-Term Regulatory Approval Of Vicineum

32. During the Class Period, Sesen Bio's prospects for future success were entirely dependent on quickly obtaining regulatory approvals for its lead product candidate, Vicineum. Approval and commercialization of Vicineum was Sesen Bio's exclusive focus, and none of its other product candidates was developed enough to have a prospect of obtaining regulatory approval or being commercialized in the near future.

33. According to Sesen Bio's 2020 annual report filed with the SEC on March 15, 2021, "[a]t this time, we are focused exclusively on the clinical development of Vicineum for the treatment of BCG-unresponsive NMIBC and have deferred further development of our other product candidates."

34. As Sesen Bio admitted in its 2020 annual report, "[w]e do not expect to generate significant revenue from the development of our product candidates unless and until we or one of our commercialization partners obtain marketing approval for, and commercialize, Vicineum for the treatment of BCG-unresponsive NMIBC."

35. Moreover, Sesen Bio's future prospects depended on achieving approval and commercialization of Vicineum as soon as possible. If regulators determined that approval of Vicineum required additional supporting trials this would likely add years of delay and tens of millions of dollars of expense to Sesen Bio's plans, which would materially harm its business.

C. Approval Of Vicineum Depended On Regulators Accepting That The VISTA Trial Sufficiently Demonstrated Safety And Efficacy

36. Sesen Bio's ability to sell Vicineum depended on regulators such as the FDA accepting its clinical trials as thoroughly demonstrating that Vicineum was both safe and effective. Regulators carefully scrutinize clinical trials in order to protect the public from dangerous or unproven medicines.

37. Sesen Bio completed three clinical trials in support of its application for regulatory approvals for Vicineum. First, Sesen Bio initiated a Phase 1 trial in 2004, purportedly designed to assess safety and determine the maximum tolerated dose. This trial enrolled 64 patients at 22 sites in Canada. This Phase 1 clinical trial was completed in April 2006.

38. Second, Sesen Bio initiated a Phase 2 trial in 2007, purportedly designed to determine the tolerability of and explore the potential for clinical benefit from Vicineum. This trial enrolled 46 patients at 20 sites in Canada and the United States. This Phase 2 clinical trial was completed in September 2009.

39. Third, Sesen Bio initiated a Phase 3 clinical trial of Vicineum, which Sesen Bio referred to as the "VISTA" trial, and which Sesen Bio intended to be its final clinical trial before

submitting applications for regulatory approvals for Vicineum. The VISTA trial was purportedly designed to test the safety and efficacy of Vicineum. Sesen Bio commenced the VISTA trial in 2015. VISTA enrolled 133 patients at 70 sites in the United States and Canada.

40. VISTA was a single-arm, non-randomized trial, meaning that all patients received Vicineum, and there was no comparison or control group that received placebo treatment or alternative treatments. VISTA completed enrollment in April 2018 and had a data cutoff date of May 29, 2019. In August 2019 Sesen Bio reported preliminary efficacy data from VISTA.

41. VISTA was the pivotal trial submitted by Sesen Bio in support of its Biologics License Application to the FDA by which it sought approval to market Vicineum in the United States. VISTA was similarly the pivotal trial underpinning Sesen Bio's other regulatory applications, such as its application to the European Medicines Agency for authorization to market Vicineum in the European Union ("E.U."). Regulators such as the FDA and EMA require a successful pivotal trial to demonstrate the safety and efficacy of a drug before they will grant approval for its marketing.

V. DEFENDANTS FAILED TO DISCLOSE MATERIAL FACTS RELATED TO THE VICINEUM APPLICATION

42. Throughout the Class Period, Defendants knew, but failed to disclose to investors, material information that created risks to approval for Sesen Bio's applications for regulatory approval to market Vicineum. Defendants failed to disclose the dangerous extent to which Vicineum leaked out of the bladder into the body, causing liver toxicity, death, and other harm to patients in its clinical trials. Defendants failed to disclose that the VISTA trial was marred by repeated investigator misconduct, which resulted in tainted data that Sesen Bio nonetheless submitted in support of its regulatory applications. And Defendants failed to disclose serious

problems raised by the EMA in private communications to Sesen Bio and its agents. These undisclosed facts undermined Defendants' misleading public statements during the Class Period.

A. Vicineum Leaked Out Of The Bladder Into The Body, Causing Elevated Liver Toxicity, Death And Other Harm To Trial Patients

43. On August 18, 2021, the health and medicine news site *STAT* published an article entitled "Sesen Bio trial of cancer drug marked by misconduct and worrisome side effects, documents show." *See* Exhibit 1. The article cited "hundreds of pages of internal documents obtained by STAT . . . confirmed by three people familiar with the matter," detailing that Sesen Bio's clinical trials for Vicineum had all along suffered from numerous problems including worrying signs of toxicity that Sesen Bio had not publicly disclosed. According to *STAT*, these internal Sesen Bio documents included safety reports, raw data, and communications between employees.

44. Vicineum is administered directly into the bladder via catheter. Vicineum contains highly toxic material that kills cells interacting with the Vicineum. According to Sesen Bio, Vicineum is supposed to only interact with cancer cells and remain exclusively in the bladder, with the Vicineum leaving the body by urination within two hours after it enters the bladder.

45. According to the documents reviewed by *STAT*, Vicineum "has led to dangerous elevations in liver enzymes that are associated with organ failure and death," which were not disclosed in Sesen Bio's SEC filings. Based on its review of Sesen Bio documents *STAT* reported that "[i]n 2016, one patient in the study was diagnosed with a drug-related case of liver failure and died within weeks." *STAT* similarly revealed that, according to Sesen Bio documents, in 2016 "a patient in VISTA died of liver failure that doctors determined was caused by Vicineum."

46. *STAT* cited Sesen Bio internal documents as revealing that "data from Sesen's clinical trials suggested Vicineum was leaking out into the body, leading to worrisome side effects." *STAT* reported that in clinical trials testing Vicineum on head and neck cancer, one patient died of liver failure, and another "matched the criteria for a clinical rule of thumb called Hy's Law, meaning a patient is at serious risk for fatal, drug-induced liver injury."

47. The term "Hy's Law" was coined in the 1980s by Robert Temple of the FDA based on an observation described by Hyman Zimmerman, one of the world's leading authorities on toxic liver injury. According to Hy's Law, drug-induced jaundice caused by hepatocellular injury, without a significant obstructive component, leads to death or liver transplantation in greater than 10% of cases or more. The major use of Hy's Law has been in the setting of drug development for assessment of a drug's potential to cause severe drug-induced liver injury ("DILI"). The regulatory definition of Hy's Law as described in the FDA's and other agencies' guidance, has been used by most drug makers worldwide, and has had a dramatic effect on data analysis and liver safety assessment during drug development. As stated in the FDA's "Guidance for Industry, Drug-Induced Liver Injury: Premarketing Clinical Evaluation," "[f]inding one Hy's Law case in the clinical trial database is worrisome; finding two is considered highly predictive that the drug has the potential to cause severe DILI when given to a larger population."

48. According to *STAT*'s review of Sesen Bio documents, a similar pattern emerged in the VISTA study of Vicineum as in the head and neck cancer study of Vicineum. In VISTA, "[o]ne patient met the criteria for Hy's Law, suggesting Vicineum led to serious liver toxicity," and "[a]nother patient was diagnosed with life-threatening, drug-induced liver failure, confirmed by biopsy."

49. According to *STAT*, internal Sesen Bio documents confirm these cases of Hy's Law in Sesen Bio's trials, including "a clinical report concluding one patient 'met the criteria for Hy's Law'," and "internal communications about a second patient in which one employee wrote 'I agree this is a Hy's Law case'."

50. According to *STAT*, Sesen Bio issued a statement in response to the article in which Sesen Bio claimed that Vicineum was not associated with life-threatening elevations in liver enzymes, however, *STAT* reported that this claim is contradicted by "multiple internal documents."

51. *STAT* news had an independent expert review the internal Sesen Bio documents that it obtained. Ben Davies, a urologist at the University of Pittsburgh Medical Center who treats bladder cancer is quoted as stating, "[i]f this is true, there are serious issues that need to be addressed before this drug can even be considered for approval," and that "[m]ost serious is this apparent liver toxicity."

B. Investigator Misconduct And Tainted Data In The VISTA Trial

52. The August 18, 2021 *STAT* news article also revealed that the VISTA trial "had more than 2,000 violations of trial protocol, including 215 classified as 'major,' according to company documents." According to the documents reviewed by *STAT*, "[t]he study's independent monitors reported three investigators to the FDA for particularly egregious violations, calling them issues of 'serious noncompliance' that 'placed subjects at risk of harm'."

53. According to *STAT*'s review of reports sent to the FDA, "[i]n 2017 and 2018, Copernicus, a firm Sesen hired to monitor its trial, found three doctors in the study were guilty of 'serious noncompliance,' 'continued noncompliance,' and actions that 'placed subjects at risk of harm'." FDA regulations provide for an Institutional Review Board ("IRB") to review and

monitor biomedical research involving human subjects. Copernicus Group Independent Review Board is a North Carolina based company providing IRB services for clinical trials.

54. According to *STAT*, "one investigator had his clinic closed in 2017 after his hospital's disciplinary committee concluded he had engaged in 'disgraceful, dishonorable, or unprofessional' behavior." And a second investigator "was found to be back-dating data," according to internal Sesen Bio documents. In both of these cases of investigator misconduct Sesen Bio documents revealed that it was advised that "the data from these affected centers cannot be used in any data analysis" submitted to the FDA. However, internal documents revealed that Sesen Bio "included results from both sites in its application for Vicineum's approval."

55. Further, according to *STAT*, Sesen Bio's statement in response to the article "did not deny the protocol violations, [or] the investigator misconduct," and similarly "did not deny any instances of investigator misconduct in VISTA and did not dispute that it submitted tainted data to the FDA."

56. In fact, Sesen Bio later confirmed certain of the facts reported by *STAT*. In a current report filed on SEC Form 8-K on October 27, 2021 Sesen Bio announced that the FDA had "published a Warning Letter issued to a former study investigator in Sesen Bio, Inc.'s . . . Phase 3 VISTA trial for Vicineum." Sesen Bio further disclosed that:

> The FDA Warning Letter indicates that the study investigator did not comply with applicable statutory requirements and applicable regulations regarding conduct of clinical investigations. The study investigator operated a clinical site that was previously part of the VISTA trial, which was closed by the Company on May 26, 2017. The study investigator's medical license was temporarily suspended on May 29, 2017 due to inaccurate recordkeeping, which was unassociated with Sesen Bio and the patients in the VISTA trial. The Company notified the FDA of the misconduct at that time.
>
> When the clinical site was closed, five patients had completed treatment and were in post-treatment follow-up. There was no evidence found that patients were

> harmed by the study investigator's actions. The Company included the corresponding patient data from the clinical site in its BLA submission to the FDA, which were thoroughly analyzed and discussed during the BLA review.

57. The FDA Warning Letter in question was issued to Dr. Joseph A. Zadra, M.D., dated October 14, 2021. The FDA Warning Letter detailed that Zadra failed to ensure that subjects met all inclusion criteria before enrollment in a study, and that certain laboratory tests be performed at specific time points in conformity with the study's investigational plan. The FDA Warning Letter concluded, "[w]e emphasize that enrollment of subjects who do not meet eligibility criteria and failure to perform safety-related labs, tests, and procedures as required by the protocol, jeopardize subject safety and welfare."

C. Regulators Warned Sesen Bio Of Serious Problems With Vicineum And The VISTA Trial

58. Sesen Bio interacted frequently with the FDA and the EMA regarding its applications to market Vicineum, but misleadingly only reported positive news about these interactions while failing to disclose the extent and seriousness of concerns expressed by regulators, and specifically concerns repeatedly expressed by the EMA.

1. Overview Of Communications Between The European Medicines Agency And Sesen Bio

59. Sesen Bio submitted a marketing authorization application ("MAA") for Vicineum to the EMA in March 2021, via its agent, DLRC Pharma Services ("DLRC"). DLRC advertises itself as providing regulatory representative services to help non-European Union companies meet E.U. pharmaceutical legislation requirements, including by acting as the applicant for marketing authorizations.

60. Although Sesen Bio's MAA was technically submitted by DLRC, Sesen Bio remained in control of, and was the intended beneficiary of, the MAA. As such, Sesen Bio received all communications from the EMA to DLRC, and controlled all communications from

DLRC to the EMA. Sesen Bio's public statements regarding the MAA refer to the MAA as belonging to Sesen Bio, and these statements do not mention DLRC.

61. Both before and after Sesen Bio's submission of the MAA, the EMA repeatedly expressed serious concerns about Vicineum and its supporting trials, including in official "assessment reports," which concerns and assessment reports Sesen Bio failed to disclose to investors.

62. Shortly after Sesen Bio announced on August 13, 2021 that the FDA had rejected its BLA for Vicineum, on August 20, 2021 Sesen Bio withdrew its MAA to the EMA. On October 20, 2021 the EMA published a "Withdrawal assessment report" regarding Sesen Bio's withdrawal of the MAA. *See* Exhibit 2.

63. Consistent with the EMA's procedures for the processing of MAAs, the withdrawal assessment report included the most recently completed assessment report from the EMA at the time of withdrawal. This most recently completed assessment report was dated July 22, 2021, and is known in the context of the EMA's MAA process as a "Day 120" assessment report. July 22, 2021 is approximately 120 days after the EMA began processing Sesen Bio's MAA on March 25, 2021.

64. Consistent with the EMA's procedures for the processing of MAAs, the EMA would have provided Day 120 assessment report to Sesen Bio on or about its July 22, 2021 date. The Day 120 assessment report details numerous serious problems with Vicineum and its supporting studies, that precluded EMA approval of Sesen Bio's MAA. The Day 120 report also provides details of prior communications between the EMA and Sesen Bio.

65. In summarizing its recommendations, the Day 120 report states, "[b]ased on the review of the data on quality, safety, efficacy, the application for Oportuzumab monatox [the

generic chemical name of Vicineum] . . . is not approvable since 'major objections' have been identified, which preclude a recommendation for marketing authorisation at the present time." The report noted that the "major objections precluding a recommendation of marketing authorisation" related to safety (including concerns about "systemic exposure"), efficacy, product quality, and the conduct of the VISTA trial and the reliability of its data. *See* Exhibit 2. It further concludes that "[t]he B/R [benefit/risk] balance is currently negative due to several MOs [major objections]," and that "[t]he overall B/R of Oportuzumab monatox . . . is negative."

66. The Day 120 report also notes that the EMA advised Sesen Bio in 2009 to conduct its pivotal study as a controlled randomized trial, but Sesen Bio simply ignored this advice and conducted a single-arm study instead. The EMA warned Sesen Bio in 2009 that "the single arm trial . . . was not considered adequate to support conditional/full MA [marketing authorization]."

67. Moreover, the report further states that Sesen Bio requested that its MAA for Vicineum be reviewed under the EMA's accelerated assessment procedure, which the EMA denied. The EMA's reasons for denying accelerated assessment included that "the product is not expected to . . . provide a therapeutic advantage compared to available treatments, survival benefit or other important benefit," that "[t]he single arm study is not considered strong evidence in this setting," and that "[t]he clinical relevance of the 3-month timepoint for complete response compared to 6 months is not clearly justified."

68. The EMA made its decision to deny accelerated assessment at its meeting held on January 25-29, 2021. Consistent with the EMA's procedures for the processing of MAAs, the EMA would have communicated its denial of accelerated assessment, and the reasons for this denial, to Sesen Bio shortly after the January 2021 meeting.

69. In addition to the severely negative findings communicated by the EMA to Sesen Bio in the Day 120 report, and the explanation of the reasons for the EMA's denial of accelerated assessment, the EMA's MAA evaluation process also involves the issuance of a "Day 80" assessment report. Consistent with the EMA's procedures for the processing of MAAs, the EMA would have provided the Day 80 report to Sesen Bio on or about June 13, 2021, and this report would have contained findings consistent with those in the Day 120 report. June 13, 2021 is 80 days after the EMA began processing Sesen Bio's MAA on March 25, 2021.

2. The EMA Raised Major Safety Concerns Regarding Vicineum

70. The Day 120 report states "83% of the patients had increased creatinine levels . . . oportuzumab monatox seems to pose significant renal toxicity," and further states:

> oportuzumab monatox has an extremely toxic payload, and the applicant is asked to discuss whether a reflux of oportuzumab monatox back to the kidney, where it potentially could be absorbed, indeed could be the reason for the unexpected findings with regard to systemic toxicity especially in terms of renal, cardiac and liver toxicity.

71. In discussing the benefit-risk assessment for Vicineum, the Day 120 report stated:

> With regards to safety, the assessment of safety is based on a limited database, with limited exposure. Long-term safety data are lacking. Concerns are raised with regard to the reliability of the safety database. The applicant claims that there is no substantial systemic absorption, but this is in stark contrast to the safety findings so far. This is based on the cardiovascular, renal and liver safety profile, and the extent of neutralising antibodies.
>
> A GCP [good clinical practice] inspection should be triggered to determine the reliability of the database.

72. Regarding the potential for harm to kidney and liver tissue, the Day 120 report states:

> The applicant states that systemic absorption from the urinary bladder is very limited and only very low plasma levels close to LLOQ [lower limit of quantification] was observed in a few patients (SmPC). Despite these statements, cases of liver toxicity and kidney failure was observed in patients indicating

> systemic absorption from the urinary bladder or at least absorption to kidney and thereafter liver.
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> * * *
>
> As a first step in the characterisation of the systemic safety profile of oportuzumab monatox after intravesical administration, the possibility for systemic absorption after intravesical instillation of VB4-845 should be investigated from the clinical point of view (see clinical safety MO [major objection]). In addition, the applicant is asked for a thorough discussion of the mechanism behind and clinical relevance of renal and hepatic toxicities, as well as for the elevated platelet levels, observed in the nonclinical and clinical studies.

73. The potential toxicity of Vicineum was further discussed in the Day 120 report:

> The evaluation of potential toxicity after intravesical instillation is not deemed sufficient. Studies using subcutaneous administration show dose dependent severity of skin tissue damage after repeat-dose administration in both rat and monkey. In light of missing local tolerance studies after intravesical instillation, the relevance of these findings in EpCAM negative tissues to the normal lining of bladder should be further discussed including the mechanism of action. Moreover, the omission of presenting toxicity studies using a clinically relevant route of administration should be further justified. Liver toxicity was observed in mice after intravenous administration and since rare incidents of liver toxicity were observed in the clinic, this should also be further elaborated upon.

74. The Day 120 report noted that the safety data reported by Sesen Bio from its clinical trials appears misleading:

> The number of AEs [adverse events] leading to discontinuation is very low, which gives the impression that oportuzumab is a well-tolerated medicinal product. However, this is in stark contrast to the safety profile of the product as discussed so far. The applicant is asked to comment on this.

75. The Day 120 report also noted that the high prevalence of adverse events in Sesen Bio's studies indicated the possibility that Vicineum was leaking into the body beyond its intended bladder target, stating "safety data suggest that there is a relation between oportuzumab systemic exposure and incidence of adverse events since there is a high percentage of events that are not expected from a medicinal product for vesical instillation." The report further states "Systemic drug exposure is suspected."

76. In summarizing its clinical safety concerns, the Day 120 report states:

> there were some observed events (gastrointestinal AEs, hepatotoxicity and signs of nephrotoxicity) that led to a suspicion about a higher than expected systemic exposure to oportuzumab. In addition, most of these events were observed also in non-clinical studies, in which a systemic route was used therefore providing some support to the observations. The applicant should discuss this issue, including a possible explanation for the observed systemic adverse events and reasons why, even though almost none of the subject samples were positive to detectable drug serum levels, it appears that systemic exposure to oportuzumab may be greater than expected and also greater than claimed.

77. The Day 120 report concludes its clinical safety discussion:

> In conclusion, the assessment of safety is based on a limited database, with limited exposure. Long-term safety data are lacking. Concerns are raised with regard to the reliability of the safety database. The applicant claims that there is no substantial systemic absorption, but this is in stark contrast to the safety findings so far. This is based on the non-intuitive patterns in the safety data, the cardio-vascular, renal and liver safety profile, and the extent of neutralising antibodies.
>
> A GCP [good clinical practice] inspection should be triggered to determine reliability of the database.

78. Despite the high prevalence of adverse events among study participants, Sesen Bio proposed a summary of safety concerns listing no safety risks and no missing safety information. In response, the Day 120 report states, "This is not acceptable, especially when bearing in mind the observed safety profile, where concerns are raised about the cardiac, renal and liver toxicity and the fact that oportuzumab has one of the most toxic payloads. There are currently also concerns with regard to systemic absorption of oportuzumab monatox." The report identified "[i]mportant identified risks" of nephrotoxicity [kidney toxicity] and hepatotoxicity [liver toxicity], and "[i]mportant potential risks" including adverse drug reactions due to systemic exposure. The report also identified "[m]issing information" regarding long-term safety.

3. The EMA Disputed Vicineum's Claimed Efficacy

79. The EMA's Day 120 report requested Sesen Bio to justify its efficacy data, stating "The clinical relevance of the primary endpoint, the short follow-up time and the duration of effect are questioned." The report noted "oportuzumab showed a lack of clinically relevant treatment effect with a poor complete response rate of 16% (CIS [carcinoma *in situ*]) at the originally endpoint of 12 months. A placebo response rate in the current setting is likely." The report further questioned Vicineum's efficacy:

> duration of the effect appears limited, with a median duration of response of approximately 9 months and only 11 patients maintaining the response at 2 years. Whether the observed efficacy results can be expected to translate into clinically meaningful benefit for patients (e.g. a delay in time to cystectomy with no detrimental effect in survival) is uncertain. Further substantiation of the reported data is needed to justify a clinical benefit in the claimed patient population.

80. Summarizing its efficacy concerns, the Day 120 report states that the EMA "has identified multiple MO's [major objections], and a triggered GCP [good clinical practice] inspection is proposed. The credibility of the study conduct, validity of the database, and the clinical meaningfulness of the data are seriously questioned."

81. Commenting on uncertainties regarding the VISTA trial, the Day 120 report notes that "approximately 16% of patients who initiate this therapy will be responders at month 12. This is not in line with recently established complete response benchmarks where a clinically meaningful CR [complete response] at 12 months is considered to be at least 30%." As such, the report concludes that the "benefit of Oportuzumab monatox in patients with NMIBC is uncertain," and "it is unclear why the study is considered successful." The report further notes "uncertainties and concerns about credibility of data."

82. The Day 120 report further notes that because the study sample size was initially calculated based on a different primary endpoint (that Sesen Bio changed during the course of

the VISTA trial), "presented sample size is not relevant to the current study." The report likewise notes that "The design and conduct of the pivotal study are not considered adequate for a pivotal study," for reasons including that the VISTA results appear to have failed to meet Sesen Bio's initially planned primary endpoint of 20% complete response at 12 months, and so the EMA notes "[t]he applicant is requested to clarify why the study is considered successful."

4. The EMA Identified Other Serious Flaws In The VISTA Trial

83. The Day 120 report notes that Sesen Bio made several substantial changes to the pivotal study's conduct, while it was ongoing, with respect to statistical analysis and inclusion criteria, which changes were poorly documented, and that as such "uncertainties and concerns about the credibility of data should trigger a GCP [good clinical practice] inspection."

84. The Day 120 report notes serious concerns relating to the potency of Vicineum:

> Information and data regarding the potency determination is difficult to comprehend and is scattered across different sections in the dossier involving both drug substance and drug product sections. Since potency determination is essential for the safety and efficacy for the drug product, a major objection has been raised encompassing the issues identified throughout the dossier. Furthermore, a major objection has been raised due to the lack of a risk evaluation for the potential formation of and contamination with N-nitrosamines in VB4-845 DP and diluent, respectively.

85. The Day 120 report rejected the primary endpoints that Sesen Bio chose to evaluate the results of the VISTA study, stating "the primary endpoint CR [complete response] at 3 months is not considered informative and the CR at 6 months is preferred. The choice of DoR [duration of response] as primary endpoint is not endorsed."

86. The Day 120 report noted inconsistencies in the VISTA patient population and the study's stated inclusion criteria: "The applicant is asked to clarify why only 78/93 subjects have CIS when all 93 subjects are expected to have CIS and why 20% in cohort 3 had CIS where no subjects are expected to have CIS."

87. The Day 120 report also rejects the proposed indications sought by Sesen Bio for Vicineum, because "the wording is not reflective of the study design."

88. In sum, the EMA made severely negative findings regarding Vicineum's safety and efficacy, and regarding the design and conduct of the pivotal VISTA trial. These findings presented material risks to Sesen Bio's MAA for Vicineum. The noted deficiencies likewise presented material risks to Sesen Bio's other regulatory applications for Vicineum, including its BLA to the FDA.

VI. DEFENDANTS SOLD $175 MILLION OF ARTIFICIALLY INFLATED STOCK

89. Sesen Bio began a program of "at the market" stock offerings in 2019, through which it could sell shares at the prevailing market price. At first Sesen Bio made only modest use of this program. However, during the Class Period, Sesen Bio dramatically increased its sales under this at the market offering program, in order to benefit from the artificially inflated price of its stock.[1]

90. On November 29, 2019, Sesen Bio entered into an Open Market Sale Agreement with Jefferies LLC, as sales agent, under which the Company could issue and sell shares of its common stock, from time to time in an at the market offering, for an aggregate sales price of up to $35 million through Jefferies. On October 30, 2020 Sesen Bio and Jeffries amended the sale agreement to permit Sesen Bio to sell an additional $50 million of shares, binging the total allowable sales to $85 million. On February 17, 2021 Sesen Bio and Jeffries amended the sale agreement to permit Sesen Bio to sell an additional $34.5 million of shares, binging the total

[1] Because a company sells its stock at market prices through such an offering, such offerings are advantageous to a company when share prices are relatively high. *See* https://www.investopedia.com/terms/a/atthemarket.asp ("The availability of an [at the market] program also allows a company to take advantage of a temporarily higher stock price, a good earnings report (typically, the best time to launch an offering is shortly after the filing of the issuer's Form 10-K or 10-Q), or an upcoming milestone event to raise money.").

allowable sales to $119.5 million. On June 1, 2021 Sesen Bio and Jeffries amended the sale agreement to remove the dollar limit on the amount of permitted share sales.

91. The following table details Sesen Bio's use of the at the market offering program before and during the Class Period:

	4q19	1q20	2q20	3q20	4q20	1q21	2q21	3q21
Net Proceeds	$1,936,000	$3,179,000	$4,774,000	$8,221,000	$19,848,000	$72,543,000	$64,261,000	$38,157,000
Issuance Costs	$212,000	$98,000	$100,000	$300,000	$464,000	$2,200,000	$2,000,000	$1,200,000
Gross Proceeds	$2,148,000	$3,277,000	$4,874,000	$8,521,000	$20,312,000	$74,743,000	$66,261,000	$39,357,000
Shares	2,062,206	3,187,359	6,636,100	6,991,953	14,492,324	30,645,702	16,482,152	9,804,475
Avg. $ / Share	$1.04	$1.03	$0.73	$1.22	$1.40	$2.44	$4.02	$4.01

92. As shown in the table above, Sesen Bio used its at the market offering to raise $175.0 million in net proceeds during the first three quarters of 2021 (roughly corresponding to the Class Period), while raising only $18.1 million in the entire year from the fourth quarter of 2019 through the third quarter of 2020 prior to the Class Period.

93. That Sesen Bio's third quarter 2021 stock sales had an average price of $4.01 per share shows that most or all of such sales were completed prior to the end of the Class Period. Sesen Bio's stock traded for approximately $4.00 per share from July 2021 through the end of the Class Period, and approximately $1.00 per share from the end of the Class Period through the end of the third quarter 2021.

94. On April 5, 2021 Sesen Bio filed a current report on SEC Form 8-K stating in relevant part:

> As of March 31, 2021, Sesen Bio, Inc. (the "Company") had cash and cash equivalents of approximately $110 million. . .
>
> With a strong balance sheet, the Company believes it is well positioned to continue to build for a successful launch ahead of the potential approval of Vicineum™ for the treatment of BCG-unresponsive non-muscle invasive bladder cancer ("NMIBC") by the U.S. Food and Drug Administration ("FDA") in August 2021. As a result, the Company will be shutting down the ATM facility

> for April and May 2021, and has no plans to execute any other form of equity financing during this time.

95. On Sesen Bio's May 10, 2021 conference call, Jeffries LLC analyst Jiale Song asked "And since you're having kind of $110 million in the bank, and what is the current cash [your OpEx your guidance]?" To which Defendant Forbes responded in relevant part, "And just with regards to the cash balance of $110 million at the end of the first quarter, we do expect that - again, although we're not guiding on cash burn -- we do expect the $110 million to be sufficient to fund operations through the fourth quarter of this year."

96. Also on the Sesen Bio May 10, 2021 conference call, Canaccord Genuity analyst John Lawrence Newman asked, "in your view, what will change in terms of the views on the company once Vicineum hits the market? Just curious as to what investors might learn over time when Vicineum or if Vicineum is approved in the market that could sort of, in your opinion, kind of change your views on the trajectory of Sesen." Defendant Cannell responded in relevant part:

> Yes. It's a good question, and we get that a lot. I will, since this is all about forward-looking statements, remind everyone of Slide 2, especially the risks and uncertainties. But we've guided that we believe, based on the comprehensive Monte Carlo simulation, that there is an 80% probability of Vicineum having peak sales of $1 billion to $3 billion. And you can use whatever P/E ratios you want, but if we're right, the company value has the potential to be much higher than our current market cap, right?

97. As of the end of the first quarter 2021, Sesen Bio told investors it would be pausing its at the market stock offerings for April and May. Nonetheless, Sesen Bio sold stock for approximately $38.2 million in net proceeds via its at the market offering from June 2021 through the end of the Class Period.

VII. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS

A. December 21, 2020 Biologics License Application Announcement

98. The Class Period begins on December 21, 2020. On that day, Sesen Bio issued a press release announcing that it had submitted a "completed Biologics License Application" to the FDA for Vicineum, and filed a current report on SEC Form 8-K attaching a copy of the press release. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

99. The top of the press release prominently featured the statements, "BLA supported by strong Phase 3 VISTA trial data and positive analytical comparability data," "Priority Review requested with potential approval in mid-2021," and "Estimated peak revenue of $1B-$3B globally, $400M-$900M projected in the US." The press release further stated:

> The BLA is supported by the pivotal Phase 3 VISTA trial, which the Company believes demonstrates a strong benefit-risk profile. The BLA also includes positive chemistry, manufacturing and controls (CMC) data that the Company believes validates the analytical comparability between clinical and commercial supply.

100. The press release quotes Defendant Cannell as stating "Our strong non-clinical and clinical data, in addition to our positive comparability data, give us confidence in the regulatory path forward."

101. The above statements identified in ¶¶ 99-100 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of

Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

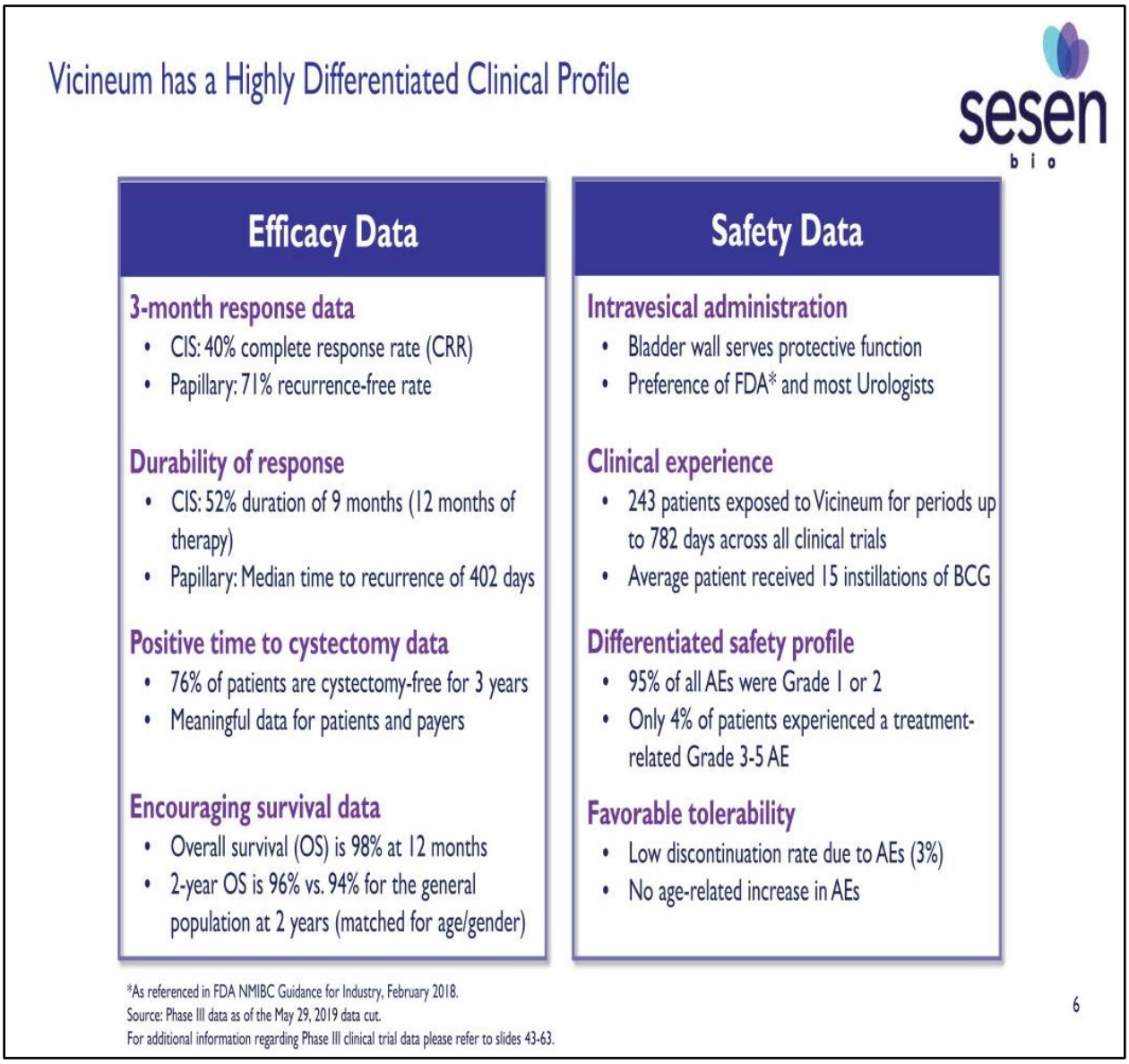
B. December 23, 2020 Corporate Presentation

102. On December 23, 2020, Sesen Bio published an investor presentation and filed a current report on SEC Form 8-K attaching a copy of the presentation. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

103. On first substantive slide, the presentation highlighted three main points, including "Clear regulatory path forward for potential approval in US in 2021 and Europe in 2022."

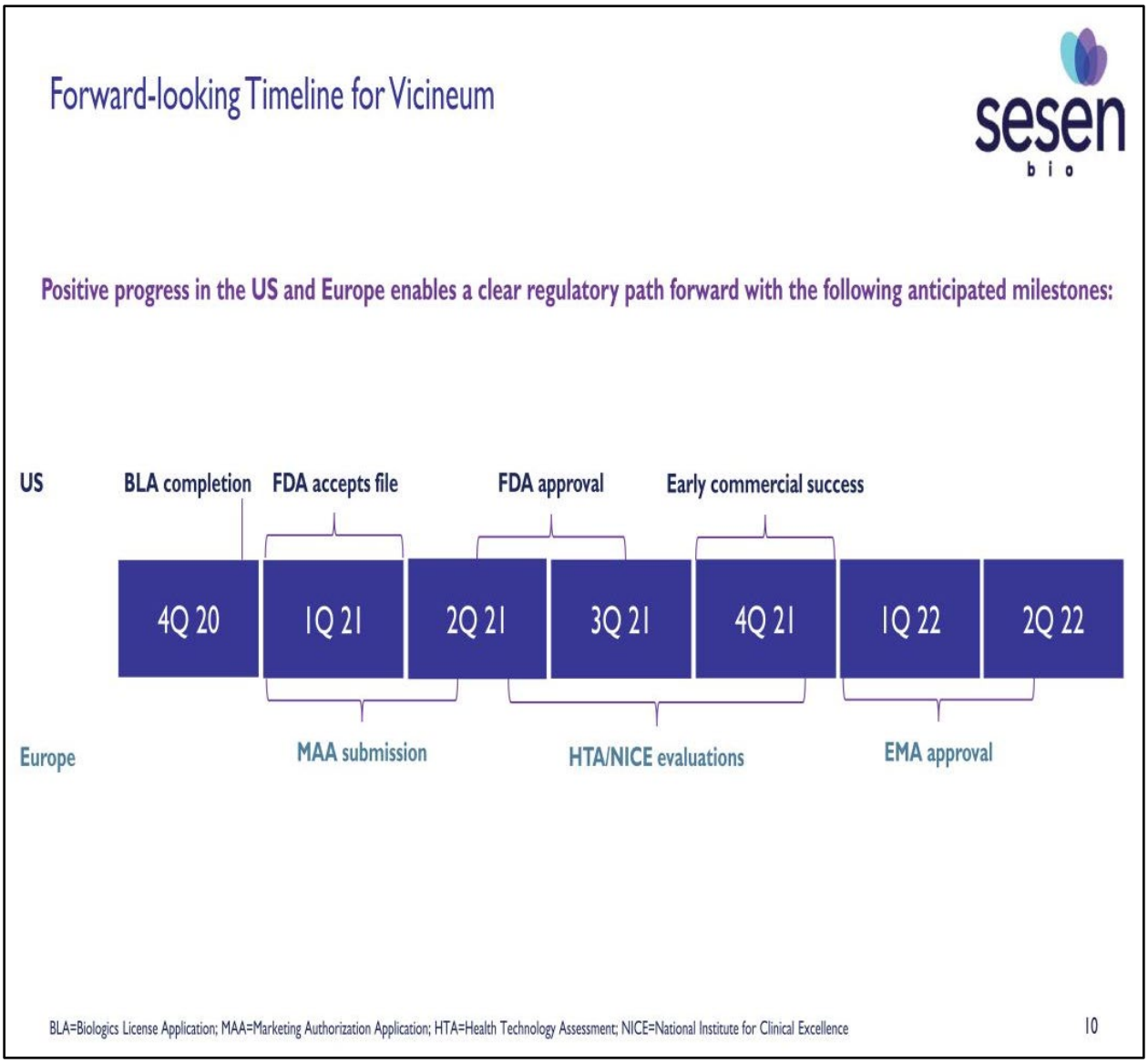
104. Under the heading "Vicineum has a Highly Differentiated Clinical Profile" the presentation touted purportedly strong safety and efficacy data:

[image on next page]



105. Under the heading "Our long-term relationship with the FDA has allowed us to shape our nonclinical and clinical programs in alignment with the agency guidance," the presentation highlighted "Nonclinical studies to determine need for evaluation of systemic toxicity," and "Consistent efficacy and safety data across Phase I, II and III trials."

106. The presentation included the following regulatory approval timeline:



107. The presentation stated under the heading "BLA for Vicnieum [*sic*] submitted on December 18, 2020," that during 2006-2015, oncology "Products with BLA Submission" had an 82% "Probability of Approval" by the FDA.

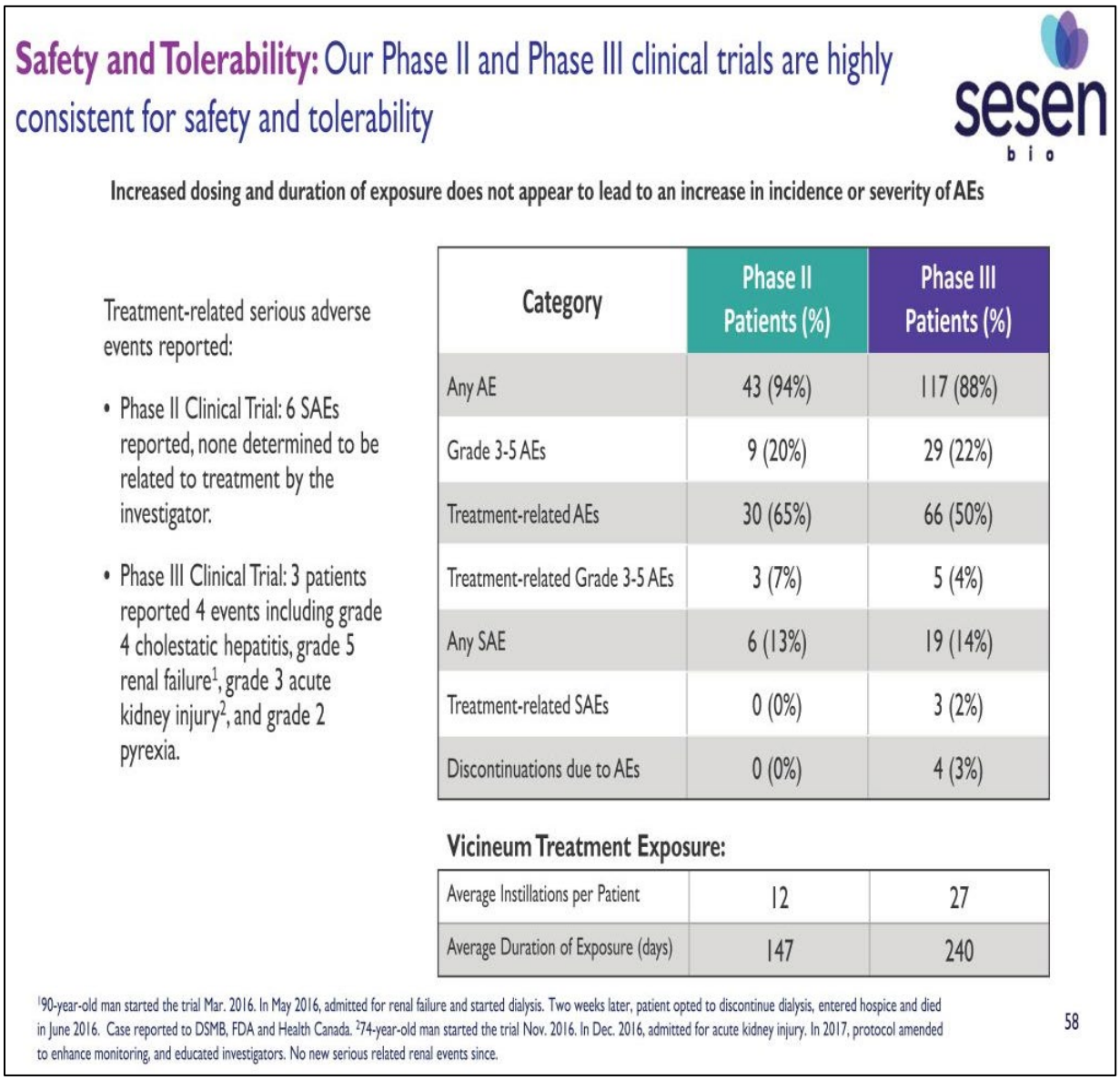
108. The presentation provided figures for "Peak Revenue Opportunity for Vicineum," which purportedly "capture 80% of uncertainty (10th-90th percentiles)." The presentation provided a peak revenue range of $450 million to $1.125 billion for Europe, and $423 million to $942 million for the United States.

109. Under the heading "Vicineum is Highly Differentiated and has a Dual Mechanism of Action" the presentation stated that Vicineum "Selectively targets cancer cells while generally sparing healthy cells." Under the heading "Vicineum demonstrates a strong benefit-risk profile in our Phase III Trial," the presentation similarly stated that Vicineum "Selectively targets cancer cells while generally avoiding healthy cells."

110. Under the heading "Compelling Clinical Data Set" the presentation highlights "Full review of safety data from Phase III," and "Full review of all tolerability data from Phase III," and touting that adverse events were "generally low grade."

111. The presentation contained the following information regarding Vicineum's purported safety and tolerability:

[image on next page]



Safety and Tolerability: Our Phase II and Phase III clinical trials are highly consistent for safety and tolerability

sesen bio

Increased dosing and duration of exposure does not appear to lead to an increase in incidence or severity of AEs

Treatment-related serious adverse events reported:

- Phase II Clinical Trial: 6 SAEs reported, none determined to be related to treatment by the investigator.
- Phase III Clinical Trial: 3 patients reported 4 events including grade 4 cholestatic hepatitis, grade 5 renal failure[1], grade 3 acute kidney injury[2], and grade 2 pyrexia.

Category	Phase II Patients (%)	Phase III Patients (%)
Any AE	43 (94%)	117 (88%)
Grade 3-5 AEs	9 (20%)	29 (22%)
Treatment-related AEs	30 (65%)	66 (50%)
Treatment-related Grade 3-5 AEs	3 (7%)	5 (4%)
Any SAE	6 (13%)	19 (14%)
Treatment-related SAEs	0 (0%)	3 (2%)
Discontinuations due to AEs	0 (0%)	4 (3%)

Vicineum Treatment Exposure:

Average Instillations per Patient	12	27
Average Duration of Exposure (days)	147	240

[1]90-year-old man started the trial Mar. 2016. In May 2016, admitted for renal failure and started dialysis. Two weeks later, patient opted to discontinue dialysis, entered hospice and died in June 2016. Case reported to DSMB, FDA and Health Canada. [2]74-year-old man started the trial Nov. 2016. In Dec. 2016, admitted for acute kidney injury. In 2017, protocol amended to enhance monitoring, and educated investigators. No new serious related renal events since.

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112. The above statements identified in ¶¶ 103-111 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had

more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

C. January 11, 2021 Revised Corporate Presentation

113. On January 11, 2021, Sesen Bio published a revised investor presentation and filed a current report on SEC Form 8-K attaching a copy of the presentation. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

114. In addition to repeating the false and misleading statements contained in the December 23, 2020 investor presentation, the January 11, 2021 version added a slide titled "Partnership Opportunity with LUMC [Leiden University Medical Center] Further Supports the Targeting Specificity of Vicineum." Under the heading "Key Highlights of Partnership" this slide stated "Next clinical trial anticipated to begin after the anticipated approval of Vicineum for NMIBC in mid-2021."

115. The above statements identified in ¶ 114 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000

violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

116. Sesen Bio published additional revised investor presentations and filed current reports on SEC Form 8-K attaching copies of the revised presentations on March 1, 2021; March 15, 2021; March 31, 2021; May 10, 2021; and June 4, 2021. The current reports were signed on behalf of Sesen Bio by Defendant Cannell. These additional revised investor presentations were substantially similar to the investor presentations dated December 23, 2020 and January 11, 2021, and each contained similar or identical false and misleading statements and omissions.

D. February 1, 2021 FDA Meeting Announcement

117. On February 1, 2021, Sesen Bio issued a press release announcing that it had held a meeting with the FDA regarding the Company's BLA for Vicineum, and filed a current report on SEC Form 8-K attaching a copy of the press release. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

118. The press release was titled "Sesen Bio Announces Successful Application Orientation Meeting (AOM) with the FDA for Vicineum™." The press release similarly stated that "on January 29, 2021 the Company participated in a productive Application Orientation Meeting with the FDA regarding its Biologic License Application (BLA) for Vicineum."

119. The press release further stated that:

> After the Company submitted its BLA to the FDA in December 2020, Sesen Bio was invited to participate in an Application Orientation Meeting, which is available in certain Center for Drug Evaluation and Research (CDER) review divisions, at the review team's discretion, for priority applications where early action is expected and/or desired.

120. The press release quoted Defendant Cannell as stating "We are very pleased with the outcome of Friday's 90-minute meeting with the FDA . . . We continue to believe Vicineum has a favorable risk-benefit profile which positions it to be best-in-class, and we are encouraged by the high level of time and engagement the FDA has demonstrated toward our review. We look forward to continuing to work with the FDA to expeditiously bring Vicineum to the market."

121. The above statements identified in ¶¶ 118-120 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

E. February 16, 2021 FDA Priority Review Announcement

122. On February 16, 2021, Sesen Bio issued a press release announcing that the FDA had accepted the Company's BLA for Vicineum, and filed a current report on SEC Form 8-K attaching a copy of the press release. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

123. The press release was titled "Sesen Bio Announces FDA Acceptance and Priority Review of its Biologics License Application for Vicineum™." The top of the press release prominently featured the statements "FDA stated it is not currently planning to hold an advisory committee meeting," and "Potential for Vicineum to be a best-in-class treatment with projected peak revenue of $1B-$3B globally, $400M-$900M in the US." The press release similarly stated:

> the U.S. Food and Drug Administration (FDA) accepted for filing the Company's Biologics License Application (BLA) for Vicineum for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), and granted the application Priority Review. In addition, the FDA stated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.

124. The press release further stated that "The FDA grants Priority Review for medicines that treat a serious condition and, if approved, would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of such serious condition."

125. The press release quoted Defendant Cannell as stating:

> We have been meeting with the FDA regularly for the past two years on the application for Vicineum . . . We understand the FDA's position and guidance very clearly and have found the review process to be collaborative and engaging. With these critical FDA decisions, we have reached an inflection point for the Company. In addition to a clear regulatory path forward, we have continued to strengthen our balance sheet in preparation for the potential launch of a product we believe represents a significant advancement over available therapies.

126. Also on February 16, 2021, the Company held a conference call to further discuss the matters addressed in its press release. In the conference call, Defendant Cannell stated:

> According to FDA guidance, priority review is awarded to products that, if approved, represent a significant improvement in safety or efficacy when compared to standard treatment. So the FDA awarding us priority rather than standard review is meaningful.

127. Defendant Cannell further stated on the conference call "probably most importantly, the FDA stated that they are not currently planning to hold an advisory committee meeting for Vicineum. This not only derisks and streamlines the regulatory path forward, it eliminates what would have been a huge workload and cost burden for a company our size."

128. Defendant Cannell further stated on the conference call:

> we have been meeting regularly with the FDA over the past 2 years, and it has been a very productive process. They have helped guide the proper submission of our preclinical, clinical and CMC manufacturing data. And through that process, we have come to understand their position and expectations for product approval, which gives us confidence in the regulatory path forward.

129. Defendant Cannell concluded the call by stating, "You can expect us to continue to be transparent and communicative. For Investor Relations, we follow a very simple formula. We tell you what we're going to do, we execute those plans, and then we tell you what we did."

130. The above statements identified in ¶¶123-129 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with

applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

F. March 8, 2021 EMA Marketing Application Announcement

131. On March 8, 2021, Sesen Bio issued a press release announcing that it had submitted a Marketing Authorization Application to the European Medicines Agency for Vicineum, and filed a current report on SEC Form 8-K attaching a copy of the press release. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

132. The press release was titled "Sesen Bio Submits Marketing Authorization Application to the European Medicines Agency for Vicineum™." The top of the press release prominently featured the statements "Follows U.S. FDA acceptance of the Biologics License Application under Priority Review," "Potential approval in Europe anticipated in early 2022," and "Significant commercial opportunity in Europe with projected peak revenue of $450M-$1.1B."

133. The press release stated:

> The MAA is supported by the pivotal Phase 3 VISTA trial data, which the Company believes demonstrates a strong risk-benefit profile. In addition, the Company believes the chemistry, manufacturing and controls (CMC) data confirms the analytical comparability between clinical and commercial supply.

134. The press release quoted Defendant Cannell as stating, "The submission of the MAA in Europe marks an important milestone as we continue toward the goal of making this potential best-in-class treatment available to patients globally . . . We will continue working collaboratively with the EMA to move Vicineum through the regulatory process as expeditiously as possible."

135. The above statements identified in ¶¶ 132-134 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

G. March 15, 2021 Annual Report And Regulatory Updates

136. On March 15, 2021, Sesen Bio issued a press release announcing its fourth quarter 2020 and full year 2020 results, and filed a current report on SEC Form 8-K attaching a copy of the press release. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

137. The press release was titled "Sesen Bio Reports Fourth Quarter and Full-Year 2020 Financial Results and Significant Regulatory and Commercial Readiness Progress for the Company's Lead Product Candidate Vicineum™." The top of the press release prominently featured the statements "Biologics License Application accepted by the FDA under Priority

Review," and "Marketing Authorization Application submitted in Europe with potential approval in early 2022."

138. The press release quoted Defendant Cannell as stating:

> We continue to make tremendous progress on our regulatory path with potential US approval later this year . . . With a strong balance sheet and clear regulatory path forward in both the US and Europe, we are positioned to fully realize the potentially significant global opportunity for Vicineum. We expect 2021 to be a transformative year for Sesen Bio and the patients we serve.

139. Under the heading "**US and European Regulatory Update**," the press release stated:

> **US:**
>
> - **On February 12, 2021, Sesen Bio received notice from the FDA that the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC was accepted for filing as of February 16th and granted Priority Review.** The FDA set an accelerated 6-month target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021 for a decision on the BLA. The FDA also stated that they are not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.
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> **Europe:**
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> - **On March 5, 2021, Sesen Bio submitted the Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Vicineum for the treatment of BCG-unresponsive NMIBC.** In December 2020, the Company successfully completed all pre-submission activities supporting the MAA. Sesen Bio anticipates potential approval of the MAA in early 2022.

(all emphasis in original).

140. Also on March 15, 2021, Sesen Bio filed its annual report on SEC Form 10-K for the period ended December 31, 2020. The annual report was signed by Defendants Cannell and Forbes, along with other Sesen Bio directors and officers.

141. Under the heading "Preliminary Safety Results," the annual report stated:

> As of the May 29, 2019 data cutoff date, in patients across all cohorts (n=133) of our Phase 3 VISTA Trial of Vicineum for the treatment of BCG-unresponsive

> NMIBC, 88% experienced at least one adverse event, with 95% of adverse events being Grade 1 or 2. The most commonly reported treatment-related adverse events were dysuria (14%), hematuria (13%) and urinary tract infection (12%) - all of which are consistent with the profile of bladder cancer patients and the use of catheterization for treatment delivery. These adverse events were determined by the clinical investigators to be manageable and reversible, and only four patients (3%) discontinued treatment due to an adverse event. Serious adverse events, regardless of treatment attribution, were reported in 14% of patients. There were four treatment-related serious adverse events reported in three patients including acute kidney injury (Grade 3), pyrexia (Grade 2), cholestatic hepatitis (Grade 4) and renal failure (Grade 5). There were no age-related increases in adverse events observed in the VISTA Trial.

142. Regarding Sesen Bio's Marketing Authorization Application to the European Medicines Agency, the annual report stated, "We held two successful meetings with the assigned Rapporteurs on November 2, 2020 and December 14, 2020 in which we received guidance on the contents of the MAA. The success of these meetings, in addition to the receipt of centralized procedure eligibility confirmation from the EMA, are significant milestones toward our regulatory path forward in Europe and supported our MAA submission on March 5, 2021, with potential approval anticipated in early 2022."

143. Regarding Sesen Bio's Biologics License Application submitted to the FDA, the annual report stated, "After we submitted the BLA to the FDA, we were invited to participate in an Application Orientation Meeting, which is available in certain Center for Drug Evaluation and Research . . . review divisions, at the review team's discretion, for priority applications where early action is expected and/or desired. "

144. Under the heading "Our TFTP Platform," regarding the targeted fusion protein therapeutics technology used by Sesen Bio, the annual report stated "Our novel TFPTs have been designed to overcome the efficacy and safety challenges of existing ADCs [antibody-drug conjugates] and are being developed for both local and systemic administration . . . We target tumor cell surface antigens that allow for rapid internalization into the targeted cancer cell and

that also have limited expression in normal cells." The annual report further stated "Local administration allows for the TFPT to reach the tumor without being cleared by the immune system, which enables us to maximize the concentration of TFPTs directly to tumors."

145. Under the heading "Our Differentiated Approach to Targeted Therapies" the annual report stated that "We believe existing ADCs have the following fundamental efficacy and safety challenges:" including:

> ***Off-target toxicities due to unstable chemical linkage between targeting antibody and cytotoxic payload.*** Existing ADCs utilize chemical linkage strategies to join antibodies to small molecule cytotoxic payloads. While in the circulatory system, these chemical linkages can break and release free cytotoxic payloads in the circulation. These free small molecule cytotoxic payloads are not targeted and cannot discriminate between dividing cancer cells and non-cancerous cells, thus resulting in increased off-target toxicities.

(emphasis in original). In contrast, the annual report stated "We believe our TFPTs offer the following key advantages:" including:

> ***Increase safety due to a more stable linkage between targeting protein and cytotoxic payload.*** Our single protein molecules are designed to remain intact until they reach the inside of the cancer cell and to not release free cytotoxins into the circulatory system, thereby minimizing off-target toxicity.

(emphasis in original).

146. Under the headings "Our Product Pipeline" and "Vicineum for the Treatment of BCG-unresponsive NMIBC," the annual report stated "Overall, we believe that our efficacy and safety data support the continued clinical development and, if approved, the commercialization of Vicineum to fulfill a significant unmet medical need in patients with BCG-unresponsive NMIBC." The annual report further stated:

> We believe that our safety data from 110 patients in our Phase 1 and Phase 2 clinical trials support further development of Vicineum for the treatment of NMIBC BCG failures. There were no Grade 4 or Grade 5 serious adverse events that were considered by the clinical investigators to be related to Vicineum during the Phase 1 and Phase 2 clinical trials of Vicineum for the treatment of NMIBC BCG failures. There was one Grade 5 serious adverse event, or death, which was

> determined by the clinical investigator to be unrelated to Vicineum. The most common reported treatment-related adverse events were an abnormally frequent passage of small amounts of urine, blood in the urine and painful urination, the majority of which were considered to be mild or moderate in severity. No patients discontinued treatment due to a Vicineum-related adverse event during the Phase 1 and Phase 2 clinical trials.

147. The annual report contained several risk disclosures which were themselves materially false and misleading because they presented as mere hypothetical risks adverse events that had already materialized, and that omitted material adverse facts. For example, the annual report purported to warn that "Clinical trial results ***may*** fail to support approval of our product candidates." (emphasis removed and emphasis added). The annual report similarly stated:

> ***If*** clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC fail to demonstrate safety and efficacy to the satisfaction of the FDA or other foreign regulatory authorities or do not otherwise produce favorable results, we ***may*** incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC.

(emphasis removed and emphasis added).

148. The annual report contained additional misleading risk disclosures:

> Vicineum for the treatment of BCG-unresponsive NMIBC ***may*** cause undesirable side effects, serious adverse events or have other properties that ***could*** delay or halt clinical trials, delay or prevent its regulatory approval, limit the commercial profile of its labeling, if approved, or result in significant negative consequences following any marketing approval.

(emphasis removed and emphasis added).

149. The annual report purported to warn that "***If*** we or any of our CROs [contract research organizations] fail to comply with applicable GCP [Good Clinical Practices], the clinical data generated in our clinical trials ***may*** be deemed unreliable and the FDA or comparable foreign regulatory authorities ***may*** require us to perform additional clinical trials before approving our marketing applications." (emphasis added).

150. The annual report also contained certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") for Defendants Cannell and Forbes attesting that, among other things, "I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2020 of Sesen Bio, Inc.," and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

151. Also on March 15, 2021 the Company held a conference call to further discuss the matters addressed in its press release and annual report. In the conference call, Defendant Forbes stated, "With the recent critical decisions made by the FDA regarding our regulatory path, we are positioned to launch a product that we believe has the potential to be best-in-class with projected global peak revenue of $1 billion to $3 billion."

152. On the conference call, Defendant Cannell stated:

> In Europe, we recently announced the submission of our MAA. This is a significant milestone for one of the largest regions in terms of unmet need for NMIBC. Our next step will be to start the pricing and reimbursement process with health technology assessment groups like NICE. We believe we have a compelling story for these economic analyses, given our clinical data set. We would then anticipate potential approval in Europe early next year.

153. Defendant Cannell further stated on the conference call, "we believe we have a clear regulatory path forward with potential approval in the U.S. in August of this year and in Europe in early 2022."

154. On the call, Jeffries LLC analyst Christopher Lawrence Howerton raised the FDA's "reevaluation of the accelerated approval of checkpoint inhibitors," asking "I'll also note that you're up for accelerated approval, so is there any risk to your reevaluation in terms of risk-benefit down the road?" Defendant Cannell responded in relevant part:

> as everyone knows, we've guided since our pre-BLA meeting with the FDA in 2019 that we expect an accelerated approval pathway for Vicineum. So for products which receive FDA accelerated approval, companies are required to conduct a study to confirm the anticipated clinical benefit. These studies are known as Phase IV confirmatory trials. If the confirmatory trial shows this drug actually provides a clinical benefit, then the FDA grants traditional approval for the drug.
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> * * *
>
> it shows why we've been working so carefully with the FDA on the design of our Phase IV confirmatory trial to make sure we meet our primary endpoints. As we disclosed in late 2019, we are targeting less than adequate BCG population for our confirmatory trial with primary endpoints of complete response rate and duration of response. And based on analyses from our Phase III study, we believe that Vicineum should be even more effective in this patient population, which has been exposed to less BCG. And so we remain confident we'll hit the endpoints in our confirmatory trial and gain traditional approval at that time.

155. In a follow up question, analyst Howerton asked, "With respect to that confirmatory study, anything about its conduct or initiation that would affect the BLA process or PDUFA?" Howerton's reference to "PDUFA" appears to mean the anticipated date for the FDA to issue a decision on Sesen Bio's BLA under the Prescription Drug User Fee Act. Defendant Cannell responded in relevant part:

> what we would like to do is initiate the study right around the time of FDA approval. And I think that's the preference of the agency as well. So we've had a Type C meeting with the FDA to discuss the protocol synopsis. We'll have a follow-up meeting with them later this spring to review the entire study protocol. And then we want to be ready to go first patient and fairly close to the time of approval and get that study underway.

156. The above statements identified in ¶¶ 137-139 and 141-155 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including

potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

157. In addition, the statements in ¶¶ 147-149 were materially false and/or misleading when made because the risk warnings presented as mere hypothetical risks adverse events that had already materialized; and the risk warnings failed to disclose specific facts concerning Vicineum's severe health risks, serious deficiencies in Sesen Bio's clinical trials, and negative assessments of Vicineum from the EMA, as detailed *supra* in Section V, that were necessary for investors to understand the magnitude and/or probability of the risks at issue.

H. March 30, 2021 Regulatory Update

158. On March 30, 2021, Sesen Bio filed a current report on SEC Form 8-K to provide a regulatory update for Vicineum. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

159. The press release stated that "The Company received notice on March 25, 2021 from the European Medicines Agency . . . that the Company's Marketing Authorization Application . . . for Vicineum was found to be valid and that the review procedure has officially started. The Company remains on-track for potential approval of Vicineum in Europe in early 2022."

160. The above statements identified in ¶ 159 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

I. May 10, 2021 First Quarter Results And Regulatory Updates

161. On May 10, 2021, Sesen Bio issued a press release regarding its first quarter results and Vicineum launch preparations, and filed a current report on SEC Form 8-K attaching a copy of the press release. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

162. The top of the press release prominently featured the statement "Company remains on track for potential approval in the US in August 2021 and in Europe in early 2022."

163. The press release quoted Defendant Cannell as stating:

> We are very pleased with the tremendous progress we continue to make in our four biggest global markets: the US, Europe, the Middle East and North Africa region and China . . . In the US, we continue to work with the FDA as we

> approach our target PDUFA date, and we are making substantial progress toward launch readiness. We are laser focused on bringing a product to market that we believe will improve patient outcomes while reducing overall healthcare costs to patients globally, and we expect to continue to make progress around the world in the coming months.

164. Under the heading "US and OUS Regulatory Update," the press release stated:

> **In February 2021, Sesen Bio received notice from the FDA that the BLA for Vicineum was accepted for filing.** Along with the acceptance, the Company was granted Priority Review with a target PDUFA date of August 18, 2021 for a decision on the BLA. The FDA also stated that an advisory committee meeting was not currently planned to discuss the BLA.

(emphasis in original). The press release further stated:

> **On March 25, 2021, the Company was notified by the European Medicines Agency (EMA) that the Company's Marketing Authorization Application (MAA) for Vysyneum™ was found to be valid and that the review procedure had officially started.** Sesen Bio submitted the MAA on March 5, 2021, and the Company remains on-track for potential approval of Vysyneum in the EU in early 2022.

(emphasis in original).

165. Under the heading "Commercial Update" the press release stated "The Company continues to build its commercial organization with key leadership appointments and a partnership with a leading contract sales organization (CSO), Syneos Health, as it prepares for the anticipated commercial launch of Vicineum in the US in 3Q 2021." (emphasis removed).

166. Also on May 10, 2021, Sesen Bio filed its quarterly report on SEC Form 10-Q for the period ended March 31, 2021. The quarterly report was signed on behalf of Sesen Bio by Defendant Cannell.

167. The quarterly report repeated the "Preliminary Safety Results" that Sesen Bio had previously provided in its annual report, as detailed in ¶ 141 *supra*.

168. The quarterly report stated, "After we submitted the BLA to the FDA, we participated in a successful Application Orientation Meeting, that is available in certain Center

for Drug Evaluation and Research . . . review divisions, at the review team's discretion, for priority applications where early action is expected and/or desired."

169. The quarterly report further stated, "The Company received notice on March 25, 2021 from the EMA that the Company's MAA for Vicineum was found to be valid and that the review procedure had officially started. The Company remains on-track for potential approval of Vicineum in Europe in early 2022."

170. The quarterly report stated "During the three months ended March 31, 2021, there were no material changes to the 'Risk Factors' included in our Annual Report on Form 10-K for the year ended December 31, 2020."

171. The quarterly report also contained certifications pursuant to the Sarbanes-Oxley Act of 2002 signed by Defendants Cannell and Forbes attesting that, among other things, "I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2021 of Sesen Bio, Inc.," and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

172. Also on May 10, 2021 the Company held a conference call to further discuss the matters addressed in its press release and quarterly report. In the conference call, Defendant Cannell stated, "we believe we have a clear regulatory path forward with potential approval in the U.S. in August of this year, and in Europe in early 2022."

173. On the call, Defendant Cannell further stated regarding U.S. approval:

> In the U.S., the team is laser-focused on responding to information requests, site inspections and preparing for the late-cycle meeting with the FDA in July. We continue to be encouraged by what we have found to be an engaging and collaborative review process. . . You can see we remain on track for our target

> PDUFA date of August 18, and our current plans are to begin promotion to physicians and patients upon potential approval in August, with commercial product supply available in urology clinics by the fourth quarter. Given the market dynamics in this market, we would expect signs of early commercial success by mid-2022.

174. On the call, Defendant Cannell further stated regarding European approval:

> In Europe, we achieved an important milestone with the conditional acceptance of our proprietary brand named Vicineum. In addition, the EMA notified us that the MAA submission was found to be valid and that the review procedure has officially started, with potential approval in early 2022.

175. Regarding expected Vicineum sales, Defendant Cannell stated on the call, "Given the differentiated value proposition of Vicineum, we expect that Vicineum will become the market leader in the non-muscle invasive bladder cancer market in late 2022, on a path to realize global peak sales of $1 billion to $3 billion."

176. On the call, Canaccord Genuity analyst John Lawrence Newman asked a question regarding "whether you would expect full approval or accelerated approval" from the FDA. Defendant Cannell responded in relevant part:

> What they haven't weighed in on yet -- we probably won't learn until right around the PDUFA date, right around August 18 -- is, whether they'll require an accelerated approval, which means a confirmatory trial, which was their previous guidance, or whether they're prepared to give full approval. So still, our guidance is the same based on what the FDA told us during the pre-BLA meeting. Our guidance is that we expect to accelerate approval, and we are ready. We have a protocol written. We're ready for a confirmatory trial, if that's their decision. And that would be great news. That would be a great event for us, is to get that accelerated approval in August. But there is the chance of the upside scenario where we actually get full approval, and so that's something well all just be watching for as we approach the PDUFA date.

177. The above statements identified in ¶¶ 162-165 and 167-176 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information

including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

178. In addition, the statements in ¶ 170 were materially false and/or misleading when made because the risk warnings presented as mere hypothetical risks adverse events that had already materialized; and the risk warnings failed to disclose specific facts concerning Vicineum's severe health risks, serious deficiencies in Sesen Bio's clinical trials, and negative assessments of Vicineum from the EMA, as detailed *supra* in Section V, that were necessary for investors to understand the magnitude and/or probability of the risks at issue.

J. June 4, 2021 Jeffries Healthcare Conference

179. On June 4, 2021, Defendant Cannell participated, on behalf of Sesen Bio, in the Jefferies 2021 Virtual Healthcare Conference and was interviewed by Jeffries LLC analyst Christopher Lawrence Howerton.

180. Howerton asked, "there has been some uncertainty in terms of whether or not there might be an advisory committee for Vicineum. That is, I guess, put to bed at this point. Is that fair?" In response Defendant Cannell stated, in relevant part:

> Yes, the FDA in February said that they do not plan on having on an AdCom. Now, the FDA can change their mind on anything at any time. But it seems to be going well the way it is.
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> * * *
>
> It is kind of a big deal if FDA decides that we do not need an AdCom. They had previously guided that they thought we would, but that was before they saw the BLA and all the data. I think it's a real nice acknowledgement of the benefit- risk profile of the product.

181. In a follow up question, Howerton stated, "They worked with industry and added this pretty detailed guidance, which you guys have kind of worked through. And I think it is a nice demonstration of your team's ability to work closely with the regulators, in my view." Defendant Cannell replied in relevant part:

> We have a really strong regulatory and clinical team and they've been able to evolve with the agency. I think that has made all the difference. There have been dozens of products that have tried to get approval for this indication – I think, often, they miss the nuances around FDA guidance. I am really proud of how our team has stuck with the FDA every step of the way.

182. Howerton asked, "The initial label you would like to see is very similar to Keytruda within this indication? What are some features that would be particularly attractive in your view?" Defendant Cannell responded in relevant part:

> I think the real differentiator is the Warnings and Precautions section. If you look at Keytruda now, there are like three pages of life-threatening immune-related AEs [adverse events]. The safety and the Warnings section is so prominent. The idea for us is that we are given intravesically. The bladder wall protects the body from the medicine. If our warnings are more about perforated bladder or bladder surgery like TURBT (transurethral resection of bladder tumor) or irritable bladder – if they are more constrained to the bladder in terms of safety warnings and precaution information, I think that is really going to resonate with physicians and that is going to drive their treatment choice.

183. Howerton asked, "you said there that the ideal label would be a full approval. You and I have discussed a confirmatory trial several times. So, I guess, what is the reconciliation between those two ideas?" Defendant Cannell responded, in relevant part:

> When we had the pre-BLA meeting in 2019, it was really good but the FDA had two specific pieces of guidance . . . they thought it would be an accelerated, not full, approval, which means you need to do a big confirmatory trial. As time has gone on and we have submitted the BLA and have had a lot of discussions with them on it—we are still guiding on accelerated approval with confirmatory trial, but as I mentioned on the last call, there's an upside scenario now where we get full approval. And that is really good for us. Not only does full approval give physicians more confidence, but, for a small company like ours, doing a big confirmatory trial is expensive, and there is a lot of work. It allows us to keep a laser focus on a world- class launch. And it takes out a lot of OpEx [operating expense], making our path to profitability quicker as well. There are a lot of benefits in that upside scenario. But we are still guiding for accelerated approval until we learn more from the agency.

184. Howerton asked, "I think we are both preparing and assuming that the drug will be approved and launched soon. So, let's talk about that commercial opportunity. First and foremost, when would you expect the product to become commercially available if approved on the PDUFA?" Defendant Cannell responded in relevant part:

> If we are approved in the August timeframe, we expect product to be available in the fourth quarter. We are still talking to the agency and trying to finalize the label. Once we agree on that label, then we need to ship that and finalize all our packaging. As you know, our fill-and-finish and all our secondary packaging is done by Baxter in Germany. Then we need to print off those labels, package them up, and ship them off to Cardinal, our distributor. That takes just a period of time and that is why I always guide product availability in the fourth quarter.

185. The above statements identified in ¶¶ 180-184 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of

Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

K. July 14, 2021 FDA Meeting Announcement

186. On July 14, 2021, Sesen Bio issued a press release announcing that it had held a meeting with the FDA regarding its BLA for Vicineum, and filed a current report on SEC Form 8-K attaching a copy of the press release. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

187. The press release was titled "Sesen Bio Announces Productive Late-Cycle Meeting with the FDA for Vicineum™." The top of the press release prominently featured the statements "No Advisory Committee meeting is planned at this time," "No confirmatory trial required at this time," and "Company believes it remains on track for August 18th target PDUFA date."

188. The press release quoted Defendant Cannell as stating:

> We are very pleased with the outcome of the Late-Cycle Meeting and continue to feel encouraged by the level of engagement from the FDA in our ongoing discussions regarding the BLA for Vicineum . . . We understand the FDA's position on the remaining review items and anticipate a successful resolution of these matters prior to the target PDUFA date. We remain focused on the patient and bringing a differentiated product to market that has the potential to improve patient outcomes while reducing overall healthcare costs.

189. The press release further stated:

Key Review Updates Include:

- The Company and the FDA discussed remaining questions related to manufacturing facilities inspection, product quality information requests and additional information related to chemistry, manufacturing and controls (CMC), and agreed upon a timeline for supporting information to be submitted.
- No Discipline Review letters have been issued to date.
- The FDA confirmed that there is no Advisory Committee meeting planned at this time.
- No issues related to risk management have been identified to date.
- No post-marketing requirements, including a confirmatory trial, have been identified as necessary at this time.
- The Company and the FDA discussed clinical trial and manufacturing post-marketing commitments required at this time.

190. The press release concluded by stating that "The FDA's review of the BLA is ongoing and the Company believes the BLA remains on track for an anticipated regulatory decision by August 18, 2021, the target PDUFA date."

191. The above statements identified in ¶¶ 187-190 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to

Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

L. July 26, 2021 Commercial Progress And Potential Approval Announcement

192. On July 26, 2021, Sesen Bio issued a press release regarding commercial progress and potential approval for Vicineum, and filed a current report on SEC Form 8-K attaching a copy of the press release. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

193. The press release was titled "Sesen Bio Announces Significant Commercial Progress as the Company Approaches the Potential Approval and Launch of Vicineum™ in the US." The press release similarly stated that Sesen Bio "has completed its commercial build phase in preparation for the anticipated launch of Vicineum, if approved, in the US, and has advanced to the implementation phase that will focus on executing the Company's commercial strategy for Vicineum."

194. The press release further stated that "If approved, promotional efforts will begin immediately, and the Company expects Vicineum product to be commercially available to physicians and patients in the fourth quarter of 2021."

195. The press release concluded by stating "The Company believes it remains on track for an FDA decision on its BLA for Vicineum by the target PDUFA date August 18, 2021."

196. The above statements identified in ¶¶ 193-195 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder

into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

M. August 9, 2021 Second Quarter Results And Regulatory Updates

197. On August 9, 2021, Sesen Bio issued a press release regarding its second quarter results and Vicineum launch preparations, and filed a current report on SEC Form 8-K attaching a copy of the press release. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

198. The press release was titled "Sesen Bio Reports Second Quarter 2021 Financial Results and Significant Global Progress for Vicineum™." The top of the press release prominently featured the statements "The Company believes it remains on track for an FDA decision on its BLA for Vicineum by August 18, 2021," and "The Company also believes it remains on track for potential approval in Europe and key markets in MENA in 2022."

199. The press release quoted Defendant Cannell as stating "We are excited about the regulatory progress we are making across our global markets."

200. Under the heading "US and Outside of the US (OUS) Regulatory Update," the press release stated:

> **On July 13, 2021, Sesen Bio participated in a productive Late-Cycle Meeting with the FDA regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC.** In the meeting, the FDA confirmed that there is no Advisory Committee meeting planned at this time, and that no post-marketing requirements, including a confirmatory trial, have been identified at this time. Also in the meeting, the Company and the FDA discussed remaining questions related to manufacturing facility inspections, product quality information requests and additional information related to chemistry, manufacturing and controls (CMC), and a timeline to submit additional supporting information was agreed upon. The Company believes it remains on track for an FDA decision on its BLA for Vicineum by the target PDUFA date of August 18, 2021.

(emphasis in original). The press release further stated:

> **In Europe, the Company believes it remains on track for potential approval of Vysyneum™ in 2022.** The Company has received the Day 80 and Day 120 questions from the European Medicines Agency (EMA) and is responding to inquiries and providing supporting information as part of the official review process.

(emphasis in original).

201. Under the heading "Commercial Planning Update" the press release stated "Promotional efforts will begin immediately upon the anticipated approval of Vicineum in the US, and the Company expects Vicineum product to be available to physicians and patients in the fourth quarter of 2021."

202. Also on August 9, 2021, Sesen Bio filed its quarterly report on SEC Form 10-Q for the period ended June 30, 2021. The quarterly report was signed on behalf of Sesen Bio by Defendant Cannell.

203. The quarterly report stated:

> On July 13, 2021, the Company participated in a productive Late-Cycle Meeting with the FDA regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC. In the meeting, the FDA confirmed that there is no Advisory Committee meeting planned at this time, and that no post-marketing requirements, including a confirmatory trial, have been identified at this time. Also in the meeting, the Company and the FDA discussed remaining questions related to manufacturing facilities inspection, product quality information requests and additional information related to chemistry, manufacturing and controls ('CMC'), and a timeline to submit additional supporting information was agreed

> upon. In the US, the Company believes it remains on track for an FDA decision on its BLA for Vicineum by the target PDUFA date of August 18, 2021.

204. The quarterly report repeated the "Preliminary Safety Results" that Sesen Bio had previously provided in its annual report, and its quarterly report for the first quarter of 2021, as detailed in ¶¶ 141 and 167 *supra*.

205. The quarterly report stated, "We received notice on March 25, 2021 from the EMA that our MAA for Vicineum was found to be valid and that the review procedure had officially started." The quarterly report further stated, "On March 31, 2021, we were informed that the Committee for Medicinal Products for Human Use of the EMA has conditionally accepted the proprietary brand name VYSYNEUM for our product candidate . . . The MAA for VYSYNEUM is currently under review with the EMA with potential approval expected in 2022."

206. The quarterly report stated "During the six months ended June 30, 2021, there were no material changes to the 'Risk Factors' included in our Annual Report on Form 10-K for the year ended December 31, 2020."

207. The quarterly report also contained certifications pursuant to the Sarbanes-Oxley Act of 2002 signed by Defendants Cannell and Forbes attesting that, among other things, "I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2021 of Sesen Bio, Inc.," and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

208. The above statements identified in ¶¶ 198-201 and 203-207 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health

risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

209. In addition, the statements in ¶ 206 were materially false and/or misleading when made because the risk warnings presented as mere hypothetical risks adverse events that had already materialized; and the risk warnings failed to disclose specific facts concerning Vicineum's severe health risks, serious deficiencies in Sesen Bio's clinical trials, and negative assessments of Vicineum from the EMA, as detailed *supra* in Section V, that were necessary for investors to understand the magnitude and/or probability of the risks at issue.

N. August 11, 2021 Potential Approval And Launch Announcement

210. On August 11, 2021, Sesen Bio issued a press release regarding leadership additions and potential approval for Vicineum, and filed a current report on SEC Form 8-K attaching a copy of the press release. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

211. The press release was titled "Sesen Bio Strengthens Executive Leadership Team as the Company Approaches the Potential Approval and Commercial Launch of Vicineum™." The top of the press release prominently featured the statement "The Company believes it remains on track for an FDA decision on its BLA for Vicineum by August 18, 2021."

212. The press release quoted Defendant Cannell as stating:

> At Sesen Bio, we believe a strong culture of compliance is a source of competitive advantage, because a thorough understanding of laws and regulatory guidance allows us to fully explore innovative commercial models and strategies . . . This enables us to do the right thing while maximizing launch uptake of Vicineum. As we near our PDUFA date, I am confident that [the newly hired Chief Compliance Officer]'s extensive experience in establishing compliance programs and enabling the implementation of innovative commercial model elements will further position us to execute a world-class launch.

213. The above statements identified in ¶¶ 211-212 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

VIII. THE TRUTH EMERGES, CAUSING SESEN BIO'S STOCK PRICE TO CRASH

A. August 13, 2021 Disclosure Of FDA Complete Response Letter

214. On August 13, 2021, during stock market trading hours, Sesen Bio issued a press release announcing that the FDA declined to approve its BLA for Vicineum in its current form. On the same day, Sesen Bio filed a current report on SEC Form 8-K attaching a copy of the press release. The current report was signed on behalf of Sesen Bio by Defendant Cannell.

215. The press release admitted that Sesen Bio had "received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its Biologics License Application (BLA) for Vicineum™." It further admitted that "The FDA has determined that it cannot approve the BLA for Vicineum in its present form and has provided recommendations specific to additional clinical/statistical data and analyses in addition to Chemistry, Manufacturing and Controls (CMC) issues pertaining to a recent pre-approval inspection and product quality."

216. On this news, the Company's share price fell $2.80 as compared to the prior day closing price, or 57%, to close at $2.11 per share on August 13, 2021, on unusually heavy trading volume.

217. The FDA's decision constituted the materialization of risks about which material facts were previously concealed from investors by Defendants' false and misleading statements and omissions. However, Sesen Bio's disclosures on August 13, 2021 only partially revealed the truth, and remained materially false and misleading.

218. Defendants have never made a copy of the FDA Complete Response Letter publicly available.

219. The press release quoted Defendant Cannell as stating:

> We are deeply disappointed by this unexpected result, and it is an unfortunate day for patients suffering from BCG-unresponsive NMIBC . . . We remain dedicated to our mission to save and improve the lives of patients by bringing new treatment options to patients, and we intend to work closely with the FDA to understand next steps.

220. The press release further stated, "The Company plans to request a Type A meeting as soon as possible with the FDA to discuss the next steps that are needed before the application may be approved."

221. The above statements identified in ¶¶ 219-220 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

B. August 16, 2021 Conference Call Regarding The FDA Rejection

222. On August 16, 2021, prior to stock market trading hours, Sesen Bio held a conference call to discuss the FDA's complete response letter with analysts and investors.

223. On the call Defendant Cannell admitted, "we will discuss with the FDA its request for additional clinical and statistical data. It appears that we will need to do a clinical trial to provide the additional efficacy and safety data necessary for the FDA to assess the benefit-risk profile, which is the basis for approval."

224. Defendant Cannell further admitted, "we need to confirm with the agency several things. First of all, we need to confirm with them that the primary endpoint should be complete response and duration of response. We will confirm that to have sufficient sample size and statistical power the trial will need to be 90 to 100 patients as described in FDA guidance. We will confirm that it needs to be a 12-months trial and will confirm the study population."

225. Defendant Cannell admitted on the call that "In the CRL, the FDA raised other questions about drug substance and drug product manufacturing, cell banks, characterization, resin reuse, reference standards, method, specifications, stability, and microbiology."

226. On the call H.C. Wainwright & Co., LLC analyst Swayampakula Ramakanth asked "So, if you are able to get a quick decision on the Type A meeting, how quickly can you get back into the clinic? And how much lead time would you need?" Defendant Cannell responded in relevant part:

> So right now, again, I mean, I want to guide conservatively and then we'll learn more, if it's a 12-month trial, that's something that -- there's going to be enrollment period, you run a 12-month trial, you get your BLA back in. And then, that would probably be in 2023. And then the FDA has a 180-day window to respond to BLAs that are submitted after CRL. So, that's kind of what we know right now and what I would say is, if we have to do a clinical trial, we would probably be projecting, resubmitting the BLA in 2023.

227. On this news, the Company's share price fell $0.89 as compared to the prior day closing price, or 42%, to close at $1.22 per share on August 16, 2021, on unusually heavy trading volume.

228. These additional details regarding the FDA's decision constituted partial corrective disclosures and the materialization of risks about which material facts were previously concealed from investors by Defendants' false and misleading statements and omissions. However, Sesen Bio's disclosures on August 16, 2021 only partially revealed the truth, and remained materially false and misleading.

229. On the call Defendant Cannell stated "We are deeply disappointed by this unexpected result," and again stated "we are disappointed by this unexpected outcome." Defendant Cannell also stated:

> Obviously, this is a very surprising turn of events given that no deficiencies, including any substantive major deficiencies in our clinical data, were raised by the FDA at the Late - Cycle Meeting on July 13th. In addition at the Late-Cycle Meeting, the FDA indicated an additional clinical trial was not identified as necessary at such time, and advisory committee meeting was not required and there were no Discipline Review letters. And last Monday, we reached agreement with the FDA on the final wording of the USPI or product label for Vicineum.

230. Also on the Sesen Bio May 10, 2021 conference call, Canaccord Genuity analyst John Lawrence Newman asked, "I'm wondering if you could start just by giving us your view on the situation that the FDA at the moment?" Defendant Cannell responded in relevant part:

> Your question, those at the macro level, and I would say, at the macro level, there is unprecedented and level of scrutiny at the FDA . . . There's been tremendously heavy, really toxic media coverage and still there's no permanent FDA commissioner. So, and several senior positions are not filled. So, there's kind of a leadership vacuum. So, here the agency is with all that going on the unbelievable pressure of trying to work during a pandemic with an extreme focus on COVID vaccines and treatments. And so, they're working on a white-hot light and it's easy to see why they might be as you say more conservative or risk-averse . . . So, when you're under pressure, the risk adverse of the safer strategy will always be to punt the ball down the field, right, and to ask for more data. So, we requested a Type A meeting. We worked on it all weekend to get -- to try to get it out as soon as we can, that will be in the fourth quarter as I mentioned. And I'm hopeful that things have calmed down by then and I still think there's a lot of potential solutions.

231. The above statements identified in ¶¶ 229-230 were materially false and/or misleading, and failed to disclose material adverse facts about Vicineum's severe health risks and serious deficiencies in Sesen Bio's clinical trials, including the facts discussed *supra* in Section V. Specifically, Defendants failed to disclose to investors material adverse information including: (1) that Sesen Bio's clinical trials showed that Vicineum leaked out from the bladder into the body, interacting with non-cancerous cells and leading to side effects including potentially fatal drug-induced liver injury; (2) that the VISTA clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (3) that three of Sesen Bio's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (4) that Sesen Bio had submitted the tainted data in connection with applications for regulatory approval to market Vicineum; (5) that the EMA had identified and raised serious concerns about Vicineum and the VISTA trial and conveyed such concerns to Sesen Bio; and (6) that, as a result of the foregoing, there were material risks to the Company's applications to market Vicineum.

C. August 18, 2021 STAT News Article

232. On August 18, 2021, prior to stock market trading hours, *STAT* published an article entitled "Sesen Bio trial of cancer drug marked by misconduct and worrisome side effects, documents show." *See* Exhibit 1.

233. As discussed *supra* in Section V, the article cited "hundreds of pages of internal documents obtained by STAT . . . confirmed by three people familiar with the matter." According to *STAT*, these internal Sesen Bio documents included safety reports, raw data, and communications between employees.

234. The *STAT* article detailed that Sesen Bio's clinical trials for Vicineum had long suffered from numerous serious problems. These problems included undisclosed signs of toxicity

associated with serious risk for fatal, drug-induced liver injury. These problems also included hundreds of major trial protocol violations, and reliance on back-dated and otherwise tainted data.

235. On this news, the Company's share price fell $0.20, or 13% as compared to the prior day closing price, to close at $1.31 per share on August 18, 2021, on unusually heavy trading volume.

IX. ADDITIONAL SCIENTER ALLEGATIONS

236. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

237. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Sesen Bio, their control over, and/or receipt and/or modification of Sesen Bio's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Sesen Bio, participated in the fraudulent scheme alleged herein.

238. The positions of the Individual Defendants give rise to a strong inference of their scienter with respect to issues relating to Vicineum, its clinical trials, and its likelihood of achieving regulatory approvals. Defendant Cannell was Sesen Bio's CEO. Defendant Forbes was Sesen Bio's CFO.

239. The Individual Defendants repeatedly held themselves out as knowledgeable regarding the operational details of Sesen Bio and the subject matter of the various misrepresentations and omissions alleged herein, which gives rise to a strong inference of their scienter. The Individual Defendants spoke on Sesen Bio's public conference calls and were quoted in Sesen Bio press releases.

240. During and leading up to the Class Period Sesen Bio was an extremely small organization. As of December 31, 2020 Sesen Bio had only 27 full-time employees. Sesen Bio had only four executive officers (including Defendants Cannell and Forbes). This allowed the Individual Defendants to have in-depth knowledge of all aspects of Sesen Bio's operations.

241. As detailed above in Section IV, leading up to and during the Class Period, developing and attempting to obtain regulatory approval for Vicineum were Sesen Bio's core operations, which gives rise to a strong inference of the Individual Defendants' scienter regarding these issues.

242. The scienter of the Individual Defendants is imputable to Sesen Bio because they were directors and/or officers of Sesen Bio acting within the scope of their authority.

243. The misrepresentations and omissions of Sesen Bio as alleged herein are of such a nature that they would have been approved by corporate officials sufficiently knowledgeable about Sesen Bio to know that those statements and omissions were misleading.

X. CLASS ACTION ALLEGATIONS

244. Lead Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Sesen Bio securities between December 21, 2020 and August 17, 2021, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are

Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

245. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Sesen Bio's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Lead Plaintiffs at this time and can only be ascertained through appropriate discovery, Lead Plaintiffs believe that there are at least hundreds or thousands of members in the proposed Class. Millions of Sesen Bio shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Sesen Bio or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

246. Lead Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

247. Lead Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

248. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Sesen Bio; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

249. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XI. LOSS CAUSATION

250. The market for Sesen Bio's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Sesen Bio's securities traded at artificially inflated prices during the Class Period. Lead Plaintiffs and other members of the Class purchased or otherwise acquired Sesen Bio's securities relying upon the integrity of the market price of the Company's securities and market information relating to Sesen Bio, and have been damaged thereby.

251. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Sesen Bio's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially

false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Sesen Bio's business, operations, and prospects as alleged herein.

252. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Lead Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Sesen Bio's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Lead Plaintiffs and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

253. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Lead Plaintiffs and the Class.

254. During the Class Period, Lead Plaintiffs and the Class purchased Sesen Bio's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

XII. APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

255. The market for Sesen Bio's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Sesen Bio's securities traded at artificially inflated prices during the Class Period. On August 12, 2021, the Company's share price closed at a Class Period high of $4.91 per share. Lead Plaintiffs and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Sesen Bio's securities and market information relating to Sesen Bio, and have been damaged thereby.

256. During the Class Period, the artificial inflation of Sesen Bio's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Lead Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Sesen Bio's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Sesen Bio and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Lead Plaintiffs and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

257. At all relevant times, the market for Sesen Bio's securities was an efficient market for the following reasons, among others:

(a) Sesen Bio shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Sesen Bio filed periodic public reports with the SEC and/or the NASDAQ;

(c) Sesen Bio regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Sesen Bio was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

258. As a result of the foregoing, the market for Sesen Bio's securities promptly digested current information regarding Sesen Bio from all publicly available sources and reflected such information in Sesen Bio's share price. Under these circumstances, all purchasers of Sesen Bio's securities during the Class Period suffered similar injury through their purchase of Sesen Bio's securities at artificially inflated prices and a presumption of reliance applies.

259. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial

prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

XIII. NO SAFE HARBOR

260. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Sesen Bio who knew that the statement was false when made.

XIV. CLAIMS

A. First Claim: Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

261. Lead Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

262. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Lead Plaintiffs and other Class members, as alleged herein; and (ii) cause Lead Plaintiffs and other members of the Class to purchase Sesen Bio's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

263. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Sesen Bio's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

264. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Sesen Bio's financial well-being and prospects, as specified herein.

265. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Sesen Bio's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Sesen Bio and its business

operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

266. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

267. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Sesen Bio's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations,

financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

268. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Sesen Bio's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Lead Plaintiffs and the other members of the Class acquired Sesen Bio's securities during the Class Period at artificially high prices and were damaged thereby.

269. At the time of said misrepresentations and/or omissions, Lead Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Lead Plaintiffs and the other members of the Class and the marketplace known the truth regarding the problems that Sesen Bio was experiencing, which were not disclosed by Defendants, Lead Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Sesen Bio securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

270. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

271. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

B. Second Claim: Violation of Section 20(a) of The Exchange Act Against the Individual Defendants

272. Lead Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

273. Individual Defendants acted as controlling persons of Sesen Bio within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Lead Plaintiffs contend are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Lead Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

274. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

275. As set forth above, Sesen Bio and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

XV. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Lead Plaintiffs and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Lead Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

XVI. JURY TRIAL DEMANDED

Lead Plaintiffs hereby demand a trial by jury.

Dated: December 6, 2021

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